

AMENDED IN ASSEMBLY AUGUST 24, 2006

AMENDED IN SENATE MAY 18, 2006

AMENDED IN SENATE APRIL 19, 2006

SENATE BILL

No. 1702

Introduced by Senator Perata

(Principal coauthor: Assembly Member Nunez)

February 24, 2006

An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to pharmacy assistance.

LEGISLATIVE COUNSEL'S DIGEST

SB 1702, as amended, Perata. Discount prescription drug program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Discount Prescription Drug Program within the department, *applicable only to prescription drugs dispensed to recipients on an outpatient basis*. The bill would require the department to negotiate drug discount agreements with drug manufacturers and ~~pursue manufacturer rebate agreements for drugs in each therapeutic category, as specified~~. The bill would authorize any licensed pharmacy and any drug manufacturer, as defined, to participate in the program. *The bill would authorize on August 1, 2010, the department to require prior authorization in the Medi-Cal program for any drug of a manufacturer if specified conditions are*

met. The bill would establish eligibility criteria and application procedures for eligible Californians to participate in the program. ~~The application process would require an applicant to attest to information provided under penalty of perjury, which would expand the definition of an existing crime, thereby imposing a state-mandated local program.~~

The bill would establish the California Discount Prescription Drug Program Fund into which all payments received under the program would be deposited. The bill would provide that moneys in the fund shall be available, upon appropriation by the Legislature, for purposes of the program.

~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that no reimbursement is required by this act for a specified reason.~~

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: ~~yes~~no.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature hereby finds and declares all of
- 2 the following:
- 3 ~~(a) The people of California find that affordability is critical in~~
- 4 *(a) Affordability is critical in* providing access to prescription
- 5 drugs for California residents, particularly the uninsured and
- 6 those with inadequate insurance.
- 7 ~~(b) The California Discount Prescription Drug Program is~~
- 8 ~~enacted by the people to enable the state to take steps to make~~
- 9 *enacted to make* prescription drugs more affordable for qualified
- 10 California residents, thereby increasing the overall health of
- 11 California residents, promoting healthy communities, and
- 12 protecting the public health and welfare.
- 13 ~~(c) It is not the intent of the state to discourage employers~~
- 14 ~~from offering or paying for prescription drug benefits for their~~
- 15 ~~employees or to replace employer-sponsored prescription drug~~
- 16 ~~benefit plans that provide benefits comparable to those made~~
- 17 ~~available to qualified California residents under this program.~~

1 SEC. 2. Division 112 (commencing with Section 130500) is
2 added to the Health and Safety Code, to read:

3
4 DIVISION 112. CALIFORNIA DISCOUNT
5 PRESCRIPTION DRUG PROGRAM

6
7 CHAPTER 1. GENERAL PROVISIONS

8
9 130500. This division shall be known, and may be cited, as
10 the California Discount Prescription Drug Program.

11 130501. For purposes of this division, the following
12 definitions shall apply:

13 (a) *“Average manufacturer’s price” has the same meaning as*
14 *this term is defined in Section 1927(k)(1) of the federal Social*
15 *Security Act (42 U.S.C. Sec. 1396r-8)(k)(1).*

16 (a)

17 (b) *“Department” means the State Department of Health*
18 *Services.*

19 (b)

20 (c) *“Eligible Californian” means a resident of the state who*
21 *meets any one or more of the following:*

22 ~~(1) A resident of the state whose total unreimbursed medical~~
23 ~~expenses equal 10 percent or more of family income and whose~~
24 ~~family income does not exceed 100 percent of the median family~~
25 ~~income in the state.~~

26 ~~(2) An individual enrolled in Medicare who may participate in~~
27 ~~this program, to the extent allowed by federal law, for~~
28 ~~prescription drugs not covered by Medicare or by an individual’s~~
29 ~~prescription drug plan with respect to an individual responsible~~
30 ~~for paying 100 percent of the cost of prescription drugs under the~~
31 ~~coverage gap provisions of the Medicare program prescription~~
32 ~~drug benefit.~~

33 ~~(3) A resident of the state who has a family income equal to or~~
34 ~~less than 350 percent of the federal poverty guidelines and does~~
35 ~~not have outpatient prescription drug coverage paid for in whole~~
36 ~~or in part by the Medi-Cal program, the Healthy Families~~
37 ~~Program, or other program funded by the state.~~

38 *(1) Has total unreimbursed medical expenses equal to at least*
39 *10 percent of his or her family’s income where the family’s*
40 *income does not exceed the state median family income.*

- 1 (2) *To the extent allowed by federal law, is enrolled in the*
2 *Medicare program, but whose prescription drugs are not covered*
3 *by the Medicare program.*
- 4 (3) *Has a family income that does not exceed 300 percent of*
5 *the federal poverty guidelines and who does not have outpatient*
6 *prescription drug coverage paid for by any one of the following:*
- 7 (A) *In whole by the Medi-Cal program.*
- 8 (B) *In whole or in part by the Healthy Families Program or*
9 *other programs funded by the state.*
- 10 (C) *In whole or in part by another third-party payer, provided*
11 *that the individual has not reached the annual limit on his or her*
12 *prescription drug coverage.*
- 13 (4) For purposes of this subdivision, the cost of drugs provided
14 under this division is considered an expense incurred by the
15 family for eligibility determination purposes.
- 16 (e)
- 17 (d) “Fund” means the California Discount Prescription Drug
18 Program Fund.
- 19 (d)
- 20 (e) “Manufacturer” means a drug manufacturer as defined in
21 Section 4033 of the Business and Professions Code.
- 22 (e)
- 23 (f) “Manufacturer’s rebate” means the rebate for an individual
24 drug or aggregate rebate for a group of drugs necessary to make
25 the price for the drug ingredients equal to or less than the
26 applicable benchmark price.
- 27 ~~(f) “Multiple-source drug” means the same drug in the same~~
28 ~~dosage form and strength manufactured by two or more~~
29 ~~manufacturers, which is approved by the United States Food and~~
30 ~~Drug Administration under provisions pertaining to the~~
31 ~~Abbreviated New Drug Applications (ANDA) process.~~
- 32 (g) “Medicaid best price” has the same meaning as this term
33 is defined in Section 1927(c)(1)(C) of the Social Security Act (42
34 U.S.C. Sec. 1396r-8)(c)(1)(C).
- 35 (h) “Multiple-source drug” has the same meaning as this term
36 is defined in Section 1927(k)(7) of the Social Security Act (42
37 U.S.C. Sec. 1396r-8)(k)(7).
- 38 (g)
- 39 (i) “National drug code” or “NDC” means the unique 10-digit,
40 three-segment number assigned to each drug product listed under

1 Section 510 of the federal Food, Drug, and Cosmetic Act (21
2 U.S.C. Sec. 360). This number identifies the labeler or vendor,
3 product, and trade package.

4 (j) *“National sales data” means prescription data obtained*
5 *from a national-level prescription tracking service.*

6 ~~(h)~~

7 (k) *“Participating manufacturer” means a drug manufacturer*
8 *that has contracted with the department to provide an individual*
9 *drug or group of drugs for the program.*

10 ~~(i)~~

11 (l) *“Participating pharmacy” means a pharmacy that has*
12 *executed a pharmacy provider agreement with the department for*
13 *this program.*

14 ~~(j)~~

15 (m) *“Pharmacy contract rate” means the negotiated per*
16 *prescription reimbursement rate for drugs dispensed to eligible*
17 *Californians. The department shall establish a single, basic*
18 *pharmacy contract rate, but may contract at different rates with*
19 *pharmacies in order to provide access throughout the state.*

20 ~~(k)~~

21 (n) *“Prescription drug” means any drug that bears the legend:*
22 *“Caution: federal law prohibits dispensing without prescription,”*
23 *“R only,” or words of similar import.*

24 ~~(l)~~

25 (o) *“Private discount drug program” means a prescription drug*
26 *discount card or manufacturer patient assistance program that*
27 *provides discounted or free drugs to eligible individuals. For the*
28 *purposes of this division, a private discount drug program is not*
29 *considered insurance or a third-party payer program.*

30 ~~(m)~~

31 (p) *“Program” means the California Discount Prescription*
32 *Drug Program.*

33 (q) *“Single-source drug” has the same meaning as this term,*
34 *and the term innovator multiple-source drug, are defined in*
35 *Section 1927(k)(7) of the Social Security Act (42 U.S.C. Sec.*
36 *1396r-8)(k)(7).*

37 ~~(n)~~

38 (r) *“Therapeutic category” means a drug or a grouping of*
39 *drugs determined by the department to have similar attributes and*

1 to be alternatives for the treatment of a specific disease or
2 condition.

3 (s) “Volume weighted average discount” means the
4 aggregated average discount for the drugs of a manufacturer,
5 weighted by each drug’s percentage of the total prescription
6 volume of that manufacturer’s drugs. Drugs excluded from
7 contracting by the department, pursuant to subdivision (d) of
8 Section 130506 and in a manner consistent with subdivision (c)
9 of Section 130506, shall be excluded from the calculation of the
10 volume weighted average discount. National sales data shall be
11 used to calculate the volume weighted average discount pursuant
12 to Section 130506. Program utilization data shall be used to
13 calculate the volume weighted average discount pursuant to
14 Section 130507.

15 130502. ~~The California Discount Prescription Drug Program~~
16 ~~is hereby established within the State Department of Health~~
17 ~~Services to use manufacturer rebates and pharmacy discounts to~~
18 ~~reduce prescription drug prices for eligible Californians. The~~
19 ~~purpose of the program is to reduce prescription drug prices and~~
20 ~~improve the quality of health care for eligible Californians. is~~
21 ~~hereby established within the department.~~

22

23 CHAPTER 2. PRESCRIPTION DRUG DISCOUNTS

24

25 130505. (a) The amount a participating, eligible Californian
26 pays for a drug through the program shall be equal to *the lower of*
27 *the participating pharmacy’s usual and customary charge or the*
28 *pharmacy contract rate pursuant to subdivision (c), less a*
29 *program discount for the specific drug or an average discount for*
30 *a group of drugs or all drugs covered by the program.*

31 (b) In determining program discounts on individual drugs, the
32 department shall take into account the rebates provided by the
33 drug’s manufacturer.

34 (c) The department may contract with participating
35 pharmacies for a rate other than the pharmacies’ usual and
36 customary rate *for prescription drugs, including multiple-source*
37 *drugs.*

38 (d) *This division shall apply only to prescription drugs*
39 *dispensed to eligible Californians on an outpatient basis.*

1 ~~130506. (a) The department shall negotiate drug discount~~
2 ~~agreements with drug manufacturers to provide for discounts for~~
3 ~~prescription drugs purchased through this program. The~~
4 ~~department shall pursue manufacturer rebate agreements for~~
5 ~~drugs in each therapeutic category.~~

6 ~~(b) The department shall attempt to obtain discounts for~~
7 ~~eligible Californians that on an average equal or exceed the~~
8 ~~Medicaid best price or a price that averages 80 percent of the~~
9 ~~lowest wholesale acquisition cost for a drug published by a~~
10 ~~wholesaler in the state generally available to the retail class of~~
11 ~~trade in the state.~~

12 ~~(c) To obtain the most favorable discounts, the department~~
13 ~~may limit the number of drugs available through the program.~~

14 ~~(d) The drug rebate agreements negotiated pursuant to this~~
15 ~~section shall be used to reduce the cost of drugs purchased by~~
16 ~~program participants.~~

17 *130506. (a) The department shall negotiate drug discount*
18 *agreements with manufacturers to provide discounts for*
19 *single-source and multiple-source prescription drugs through the*
20 *program. The department shall attempt to negotiate the*
21 *maximum possible discount for an eligible Californian. The*
22 *department shall attempt to negotiate, with each manufacturer,*
23 *discounts to offer single-source prescription drugs under the*
24 *program at a volume weighted average discount that is equal to*
25 *or below any one of the following benchmark prices:*

26 *(1) Eighty-five percent of the average manufacturer price for*
27 *a drug, as published by the Centers for Medicare and Medicaid*
28 *Services.*

29 *(2) The lowest price provided to any nonpublic entity in the*
30 *state by a manufacturer to the extent that the Medicaid best price*
31 *exists under federal law.*

32 *(3) The Medicaid best price, to the extent that this price exists*
33 *under federal law.*

34 *(b) The department may require the drug manufacturer to*
35 *provide information that is reasonably necessary for the*
36 *department to carry out its duties pursuant to this division.*

37 *(c) The department shall pursue manufacturer discount*
38 *agreements to ensure that the number and type of drugs*
39 *available through the program is sufficient to give an eligible*
40 *Californian a formulary comparable to the Medi-Cal list of*

1 contract drugs, or if this information is available to the
2 department, a formulary that is comparable to that provided to
3 CalPERS enrollees.

4 (d) To obtain the most favorable discounts, the department
5 may limit the number of drugs available through the program.

6 (e) The drug discount agreements negotiated pursuant to this
7 section shall be used to reduce the cost of drugs purchased by
8 program participants.

9 (f) All information reported by a manufacturer to, negotiations
10 with, and agreements executed with, the department or its
11 third-party vendor pursuant to this section, shall be considered
12 confidential and corporate proprietary information. This
13 information shall not be subject to disclosure under the
14 California Public Records Act (Chapter 3.5 (commencing with
15 Section 6250) of Division 7 of Title 1 of the Government Code).
16 The Bureau of State Audits and the Controller shall have access
17 to pricing information in a manner that is consistent with their
18 access to this information under the Medi-Cal program and
19 under law. The Bureau of State Audits and the Controller may
20 use this information only to investigate or audit the
21 administration of the program. Neither the Bureau of State
22 Audits, the Controller, nor the department may disclose this
23 information in a form that identifies a specific manufacturer or
24 wholesaler or prices charged for drugs of this manufacturer or
25 wholesaler. Information provided to the department pursuant to
26 subdivision (e) of Section 130530 shall not be affected by the
27 confidentiality protections established by this subdivision.

28 (e)

29 (g) (1) Any pharmacy licensed pursuant to Chapter 9
30 (commencing with Section 4000) of Division 2 of the Business
31 and Professions Code may participate in the program.

32 (2) Any drug manufacturer may participate in the program.

33 ~~130507. (a) The department shall attempt to negotiate drug~~
34 ~~discount agreements with drug manufacturers for a period not to~~
35 ~~exceed three years from January 1, 2007. At that time, the~~
36 ~~department shall make a determination as to whether:~~

37 ~~130507. (a) On August 1, 2010, the department shall~~
38 ~~determine whether manufacturer participation in the program~~
39 ~~has been sufficient to meet both of the following benchmarks:~~

1 (1) The number and type of drugs available through the
2 program ~~is~~ *are* sufficient to give eligible Californians a formulary
3 ~~comparable to that provided to Medi-Cal beneficiaries or, if this~~
4 ~~comparable to the Medi-Cal list of contract drugs or, if this~~
5 information is available to the department, a formulary
6 comparable to that provided to CalPERS enrollees.

7 ~~(2) The discounts for the drugs on an average equal or exceed~~
8 ~~the threshold in subdivision (b) of Section 130506.~~

9 ~~(3) Manufacturer participation has been sufficient to provide~~
10 ~~discounts on a range of drugs consistent with this section.~~

11 ~~(b) If the department determines that any one of the thresholds~~
12 ~~in this section is not met, then the department shall implement~~
13 ~~Sections 130508 and 130509.~~

14 ~~(2) The volume weighted average discount of single-source~~
15 ~~prescription drugs offered pursuant to this program is equal to~~
16 ~~or below any one of the benchmark prices described in~~
17 ~~subdivision (a) of Section 130506.~~

18 ~~(b) On and after August 10, 2010, the department shall~~
19 ~~reassess program outcomes, at least once every year, consistent~~
20 ~~with the benchmarks described in subdivision (a).~~

21 130508. ~~(a) Consistent with federal law, the department shall~~
22 ~~seek to contract for a net price comparable to or lower than the~~
23 ~~Medicaid best price for drugs covered by the California Discount~~
24 ~~Prescription Drug Program.~~

25 ~~(b) To the maximum extent possible, the department shall~~
26 ~~assure that enrollment and other administrative actions are~~
27 ~~seamless to all eligible Californians, whether the eligible~~
28 ~~Californian is enrolled in a program administered consistent with~~
29 ~~this section or with Section 130507. seamless to all eligible~~
30 ~~Californians.~~

31 130509. ~~(a) To the extent permitted by federal law, the~~
32 ~~department may require prior authorization in the Medi-Cal~~
33 ~~program for any drug of a manufacturer that if the manufacturer~~
34 ~~fails to agree to a price comparable to or lower than the Medi-Cal~~
35 ~~best price for prescription drugs purchased under this division.~~
36 ~~volume weighted average discount for single-source prescription~~
37 ~~drugs that is equal to or below any one of the benchmark prices~~
38 ~~described in subdivision (a) of Section 130506 and only to the~~
39 ~~extent that this requirement does not increase costs to the~~
40 ~~Medi-Cal program, as determined pursuant to subdivision (c).~~

1 (b) If prior authorization is required for a drug pursuant to this
2 section, a Medi-Cal beneficiary shall not be denied the continued
3 use of a drug that is part of a prescribed therapy until that drug is
4 no longer prescribed for that beneficiary's therapy. The
5 department shall approve or deny requests for prior authorization
6 necessitated by this section as required by state or federal law.

7 (c) *The department, in consultation with the Department of*
8 *Finance, shall determine the fiscal impact of placing a drug on*
9 *prior authorization pursuant to this section. In making this*
10 *determination, the department shall consider all of the following:*

11 (1) *The net cost of the drug, including any rebates that would*
12 *be lost if the drug is placed on prior authorization.*

13 (2) *The projected volume of purchases of the drug, before and*
14 *after the drug is placed on prior authorization, considering the*
15 *continuity of care provisions set forth in subdivision (b).*

16 (3) *The net cost of comparable drugs to which volume would*
17 *be shifted if a drug is placed on prior authorization, including*
18 *any additional rebates that would be received.*

19 (4) *The projected volume of purchases of comparable drugs,*
20 *before and after the drug is placed on prior authorization.*

21 (5) *Any other factors determined by the department to be*
22 *relevant to a determination of the fiscal impact of placing a drug*
23 *on prior authorization.*

24 ~~(e) This section shall be implemented in a manner consistent~~
25 ~~with federal law.~~

26 (d) *This section shall be implemented only to the extent*
27 *permitted under federal law, and in a manner consistent with*
28 *state and federal laws.*

29 (e) *This section may apply to any manufacturer that has not*
30 *negotiated with the department.*

31 (f) *The department shall notify the Speaker of the Assembly*
32 *and the President pro Tempore of the Senate that the department*
33 *is requiring prior authorization no later than five days after*
34 *making this requirement.*

35 (g) (1) *Subject to paragraph (2), this section shall become*
36 *operative on August 1, 2010.*

37 (2) *This section shall become operative only if the department*
38 *determines that participation by manufacturers has been*
39 *insufficient to meet both of the benchmarks identified in Section*
40 *130507.*

1 130510. The names of manufacturers of *single-source drugs*
2 that do or do not enter into ~~rebate discount~~ agreements with the
3 department pursuant to this division shall be public information
4 and shall be posted on the department's Internet Web site ~~at the~~
5 ~~time when the rebate~~ *when the discount* agreements are reached
6 *or the manufacturer ends negotiations*, commencing within six
7 months after the initial implementation date of this ~~article~~
8 *division* and updated on the first of each month thereafter.

9 130511. (a) Each drug ~~rebate discount~~ agreement shall do all
10 of the following:

11 (1) Specify which of the manufacturer's drugs are included in
12 the agreement.

13 (2) Permit the department to remove a drug from the
14 agreement if there is a dispute over the drug's utilization.

15 ~~(3) Require the manufacturer to make a rebate payment to the~~
16 ~~department for each drug specified under paragraph (1)~~
17 ~~dispensed to a program participant.~~

18 ~~(4) Require the manufacturer to make the rebate payments to~~
19 ~~the department on at least a quarterly basis.~~

20 ~~(5) Require the manufacturer to provide, upon the request of~~
21 ~~the department, documentation to validate the rebate.~~

22 ~~(6)~~

23 (3) Permit a manufacturer to audit claims for the drugs the
24 manufacturer provides under the program. Claims information
25 provided to manufacturers shall comply with all federal and state
26 privacy laws that protect a program participant's health
27 information.

28 (b) *In addition to the requirements of subdivision (a), each*
29 *drug discount agreement with a single-source manufacturer shall*
30 *do all of the following:*

31 (1) *Require the manufacturer to make a rebate payment to the*
32 *department for each drug described in paragraph (1) of*
33 *subdivision (a) dispensed to a program participant.*

34 (2) *Require the manufacturer to make the rebate payments to*
35 *the department on at least a quarterly basis.*

36 (3) *Require the manufacturer to provide, upon request,*
37 *documentation to validate the rebate.*

38 ~~(b)~~

39 (c) The department may collect prospective rebates from
40 *single-source* manufacturers for payment to pharmacies. The

1 amount of the prospective ~~rebate~~ *discount* shall be specified in
2 the drug rebate agreements.

3 ~~(e)~~

4 *(d)* (1) Manufacturers shall calculate and pay interest on late
5 or unpaid rebates. The interest shall not apply to any prior period
6 adjustments of unit rebate amounts or department utilization
7 adjustments.

8 (2) For ~~state rebate payments~~ *rebate payments to the program*,
9 manufacturers shall calculate and pay interest on late or unpaid
10 rebates for quarters that begin on or after January 1, 2007.

11 ~~(d)~~

12 *(e)* Interest required by subdivision ~~(e)~~ *(d)* shall begin accruing
13 38 calendar days from the date of mailing of the invoice,
14 including supporting utilization data sent to the manufacturer.
15 Interest shall continue to accrue until the date of mailing of the
16 manufacturer's payment. Interest rates and calculations for
17 purposes of this section shall be at 10 percent.

18 ~~(e)~~

19 *(f)* A participating manufacturer shall clearly identify all
20 rebates, interest, and other payments, and payment transmittal
21 forms for the program, in a manner designated by the
22 department.

23 130512. (a) The department shall generate a monthly report
24 that, at a minimum, provides all of the following:

25 (1) Drug utilization information.

26 (2) Amounts paid to pharmacies.

27 (3) *Program discounts compared to the usual customary price.*

28 ~~(3) Amounts~~

29 (4) *Aggregate amounts* of rebates collected from
30 manufacturers.

31 ~~(4)~~

32 (5) A summary of the problems or complaints reported
33 regarding the program.

34 (b) Information provided in paragraphs (1), (2), and (3) of
35 subdivision (a) shall be at the national drug code level.

36 *(c) The department shall generate an annual report that, in*
37 *addition to the information described in subdivision (a), reports*
38 *on the number of all of the following:*

39 (1) *Individuals enrolled.*

40 (2) *Individuals receiving a prescription under the program.*

- 1 (3) *Participating pharmacies.*
- 2 (4) *Participating manufacturers.*
- 3 (d) *All reports shall be made available on the department's*
- 4 *Internet Web site.*
- 5 130513. (a) The department shall establish and maintain a
- 6 claims processing system that complies with all of the following
- 7 requirements:
- 8 (1) Charges a price that meets the requirements of this
- 9 division.
- 10 (2) Provides the pharmacy with the dollar amount of the
- 11 discount to be returned to the pharmacy.
- 12 (3) Provides drug utilization review warnings to pharmacies
- 13 consistent with the drug utilization review standards provided in
- 14 federal law.
- 15 (b) The department shall pay a participating pharmacy the
- 16 discount provided to program participants pursuant to this
- 17 division by a date that is not later than two weeks after the claim
- 18 is received.
- 19 (c) The department shall develop a mechanism for the
- 20 program participants to report problems or complaints.

21
22 CHAPTER 3. APPLICATION, ENROLLMENT, AND OUTREACH

- 23
- 24 130520. (a) The department shall develop an application and
 - 25 reapplication form for the determination of a resident's eligibility
 - 26 for the program. An applicant, or a guardian or custodian of an
 - 27 applicant, may apply or reapply on behalf of the applicant and
 - 28 the applicant's spouse and children.
 - 29 (b) The application shall, at a minimum, do all of the
 - 30 following:
 - 31 (1) Specify the information that an applicant or the applicant's
 - 32 representative must include in the application.
 - 33 (2) Require that the applicant, or the applicant's guardian or
 - 34 custodian, attest that the information provided in the application
 - 35 is accurate to the best knowledge and belief of the applicant or
 - 36 the applicant's guardian or custodian.
 - 37 (3) Specify that the application fee due upon submission of the
 - 38 applicable form is ten dollars (\$10) annually.

1 (c) In assessing the income requirement for eligibility, the
2 department shall use the income information reported on the
3 application and not require additional documentation.

4 (d) An application may be completed at any pharmacy,
5 physician office, or clinic participating in the program through an
6 Internet Web site or call center staffed by trained operators
7 approved by the department. A pharmacy, physician's office,
8 clinic, or nonprofit community organization that completes the
9 application ~~shall~~ *may* keep the application fee as reimbursement
10 for its processing costs. If it is determined that the applicant is
11 already enrolled in the program, the fee shall be returned to the
12 applicant and the applicant shall be informed of his or her current
13 status as a program participant.

14 (e) The department shall utilize a secure electronic application
15 process that can be used by a pharmacy, physician's office, or
16 clinic, by an Internet Web site, by a call center staffed by trained
17 operators, by a nonprofit community organization, or through the
18 third-party vendor to enroll applicants in the program.

19 (f) During the department's normal working hours, the
20 department shall make a determination of eligibility within 24
21 hours of receipt by the program of a completed application. The
22 department shall mail the program participant an identification
23 card no later than seven days after eligibility has been
24 determined.

25 (g) For applications submitted through a pharmacy, the
26 department may issue a participant identification number for
27 eligible applicants to the pharmacy for immediate access to the
28 California Discount Prescription Drug Program.

29 (h) Any program participant that has been determined to be
30 eligible shall be enrolled for 12 months, or until the program
31 participant notifies the department of an intent to end enrollment.

32 (i) The department shall notify a program participant of
33 termination of enrollment 30 days prior to the termination.

34 (j) A person shall be required to apply pursuant to this section
35 for each 12-month period of eligibility.

36 130521. (a) The department may conduct an outreach
37 program to inform California residents of their opportunity to
38 participate in the program. The department shall coordinate
39 outreach activities with the California Department of Aging, *the*
40 *Employment Development Department*, and other state and local

1 agencies, and nonprofit organizations that serve residents who
2 may be eligible for the program. No outreach material shall
3 contain the name or likeness of a drug.

4 (b) The department may accept on behalf of the state any gift,
5 bequest, or donation of outreach services or materials to inform
6 residents about the program. The name of the organization
7 sponsoring the materials shall in no way appear on the material
8 but shall be reported to the public and the Legislature as
9 otherwise provided by law.

10 ~~130522. (a) A drug dispensed pursuant to prescription,~~
11 ~~including a drug dispensed without charge to the consumer, shall~~
12 ~~be accompanied by the California Discount Prescription Drug~~
13 ~~Program participation information in a manner approved by the~~
14 ~~department and as permitted by law.~~

15 ~~(b) The information shall include advice to consult a health~~
16 ~~care provider or pharmacist about access to drugs at lower prices.~~

17 ~~(c) The requirements of this section may be met by the~~
18 ~~distribution of a separate information form that is approved by, or~~
19 ~~produced and distributed by, the department.~~

20

21 CHAPTER 4. PHARMACEUTICAL MANUFACTURER PATIENT
22 ASSISTANCE PROGRAMS

23

24 130530. (a) The department shall encourage a participating
25 manufacturer to maintain those private discount drug programs
26 that are comparable to or more extensive than those provided
27 prior to the enactment of this division. To the extent possible, the
28 department shall encourage a participating manufacturer to
29 simplify the application and eligibility processes for its private
30 discount drug program.

31 (b) The department ~~shall~~ *may* execute agreements with drug
32 manufacturers and other private patient assistance programs to
33 provide a single point of entry for eligibility determination and
34 claims processing for drugs available through those programs *to*
35 *the extent permitted by state and federal law.*

36 (c) The department shall develop a system to provide a
37 program participant under this division with the best discounts on
38 prescription drugs that are available to the participant through
39 this program or through a drug manufacturer or other private
40 patient assistance program.

1 (d) (1) The department may require an applicant to provide
 2 additional information to determine the applicant's eligibility for
 3 other discount card and patient assistance programs.

4 (2) The department shall not require an applicant to participate
 5 in a drug manufacturer patient assistance program or to disclose
 6 information that would determine the applicant's eligibility to
 7 participate in a drug manufacturer patient assistance program in
 8 order to participate in the California Discount Prescription Drug
 9 Program.

10 (e) In order to verify that California residents are being served
 11 by drug manufacturer patient assistance programs, the
 12 department shall require drug manufacturers to provide the
 13 department annually with all of the following information:

14 (1) The total value of the manufacturer's drugs provided at no
 15 or very low cost to California residents during the previous year.

16 (2) The total number of prescriptions or 30-day supplies of the
 17 manufacturer's drugs provided at no or very low cost to
 18 California residents during the previous year.

19 (f) The California Discount Prescription Drug Program card
 20 issued pursuant to this division shall serve as a single point of
 21 entry for drugs available pursuant to subdivision (a), and shall
 22 meet all legal requirements for a health benefit card.

23

24 CHAPTER 5. ADMINISTRATION

25

26 ~~130540. Contracts entered into for purposes of this division~~
 27 ~~are exempt from Part 2 (commencing with Section 10100) of~~
 28 ~~Division 2 of the Public Contract Code. Contracts with~~
 29 ~~pharmacies and drug manufacturers may be entered into on a bid~~
 30 ~~or nonbid basis.~~

31 *130540. (a) Contracts, contract amendments, change orders,*
 32 *change requests, and any project or systems development*
 33 *notices, entered into for purposes of this division, shall be subject*
 34 *to the same exemptions provided for in the Medi-Cal drug*
 35 *program and those provided to the department in paragraph (4)*
 36 *of subdivision (c) of Section 124977. In addition, contracts,*
 37 *contract amendments, change orders, change requests, and any*
 38 *project or systems development notices, entered into for purposes*
 39 *of this division, are specifically exempt from:*

1 (1) Part 2 (commencing with Section 10100) of Division 2 of
2 the Public Contract Code.

3 (2) The competitive bidding requirements of State
4 Administrative Manual Management Memo 03-10.

5 (3) The project authority requirements of State Administrative
6 Manual, Section 4800 et seq.

7 (4) Section 11.00 and Provision 6 of Item 4260-001-0001 of
8 Section 2 of the Budget Act of 2006 and related Budget letters.

9 (b) Contracts with pharmacies and drug manufacturers may
10 be entered into on a bid or nonbid basis.

11 (c) Change orders entered into pursuant to this division shall
12 not require a contract amendment.

13 (d) To the extent that any exemption set forth in this section
14 conflicts with exemptions set forth in paragraph (4) of
15 subdivision (c) of Section 124977, the exemption in this section
16 shall govern over the conflicting provision in Section 124977.

17 130541. To implement the program, the department may
18 contract with a third-party vendor or utilize existing health care
19 service provider enrollment and payment mechanisms, including
20 the Medi-Cal program's fiscal intermediary. Drug—rebate
21 ~~contracts~~ discount agreements negotiated by a third party shall be
22 subject to review by the department. The department may cancel
23 a contract that it finds not in the best interests of the state or
24 program participants. *Participating pharmacy contracts entered*
25 *into pursuant to Section 130505 shall be considered contracts*
26 *between the participating pharmacy and the department and*
27 *shall not be associated with, or leveraged against, other third*
28 *party agreements.*

29 130542. (a) The department shall deposit all payments the
30 department receives pursuant to this division into the California
31 Discount Prescription Drug Program Fund, which is hereby
32 established in the State Treasury.

33 (b) Moneys in the fund shall be made available to the
34 department, upon appropriation by the Legislature, for purposes
35 of the program. Notwithstanding any other provision of law, no
36 money in the fund is available for expenditure for any other
37 purpose or for loaning or transferring to any other fund, including
38 the General Fund. The fund shall also contain any interest
39 accrued on moneys in the fund.

1 130543. (a) The director may adopt regulations as are
2 necessary for the initial implementation of this division. The
3 adoption, amendment, repeal, or readoption of a regulation
4 authorized by this section is deemed to be necessary for the
5 immediate preservation of the public peace, health and safety, or
6 general welfare, for purposes of Sections 11346.1 and 11349.6 of
7 the Government Code, and the department is hereby exempted
8 from the requirement that it describe specific facts showing the
9 need for immediate action. *necessary to implement and*
10 *administer this division.*

11 (b) ~~As an alternative to the adoption of regulations pursuant to~~
12 ~~subdivision (a), and notwithstanding Chapter 3.5 (commencing~~

13 *(b) Notwithstanding Chapter 3.5 (commencing with Section*
14 *11340) of Part 1 of Division 3 of Title 2 of the Government*
15 *Code, the director may implement this division, in whole or in*
16 *part, by means of a provider bulletin or other similar instructions,*
17 *without taking regulatory action, provided that no bulletin or*
18 *other similar instructions shall remain in effect after July 31,*
19 *2007. August 1, 2011. It is the intent that regulations adopted*
20 *pursuant to this subdivision shall be in place on or before July 31,*
21 *2007. this section shall be adopted on or before August 1, 2011.*

22 130544. *If any provision of this division, or the application*
23 *thereof, is for any reason, held invalid, ineffective, or*
24 *unconstitutional by a court of competent jurisdiction, the*
25 *remainder of this division, or the application of this provision,*
26 *shall not be affected thereby, and to this end the provisions of*
27 *this division are severable. The Legislature finds and declares*
28 *the following: Section 2 of this act, which adds Section 130506 to*
29 *the Health and Safety Code, imposes a limitation on the public's*
30 *rights of access to the writings of public officials and agencies*
31 *within the meaning of Section 3 of Article I of the California*
32 *Constitution. Pursuant to that constitutional provision, the*
33 *Legislature makes the following findings to demonstrate the*
34 *interest protected by this limitation and the need for protecting*
35 *that interest:*

36 *In order to facilitate manufacturer participation and deliver*
37 *affordable prescription drugs to low-income Californians, it is*
38 *necessary to protect the confidentiality trade secrets and pricing*
39 *information.*

1 ~~SEC. 3. No reimbursement is required by this act pursuant to~~
2 ~~Section 6 of Article XIII B of the California Constitution because~~
3 ~~the only costs that may be incurred by a local agency or school~~
4 ~~district will be incurred because this act creates a new crime or~~
5 ~~infraction, eliminates a crime or infraction, or changes the~~
6 ~~penalty for a crime or infraction, within the meaning of Section~~
7 ~~17556 of the Government Code, or changes the definition of a~~
8 ~~crime within the meaning of Section 6 of Article XIII B of the~~
9 ~~California Constitution.~~

O